

EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Media and Reagents: Examination and Expiration Time

SOP Number: QC-10-03

Date Revised: 11-07-05

Initiated By: _____ Date: ____/____/____

Print Name: _____

Technical Review: _____ Date: ____/____/____

Print Name: _____

Technical Staff

QA Review: _____ Date: ____/____/____

Print Name: _____

QA Officer

Approved By: _____ Date: ____/____/____

Print Name: _____

Branch Chief

Effective Date: ____/____/____

Controlled Copy No.: _____

Withdrawn By: _____ Date: ____/____/____

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1.0 SCOPE AND APPLICATION:

1.1 This protocol establishes expiration dates for media and reagents used in conjunction with efficacy testing of disinfectants, and describes the procedure for visual assessment of stored sterilized media.

2.0 DEFINITIONS:

2.1 DI = de-ionized water

2.2 Target Volume = required volume of media

3.0 HEALTH AND SAFETY: Not applicable

4.0 CAUTIONS:

4.1 Products will not be used past the manufacturer's recommended expiration date.

5.0 INTERFERENCES:

5.1 If storage conditions for the media have been compromised in any way, then the media will be discarded.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the recommended expiration times for the various media used, and the procedures for visual assessment of media. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS: None

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE:

9.1 Refer to section 10.0 for storage conditions.

10.0 PROCEDURE AND ANALYSIS:

10.1 Liquid Media/Reagents:

- 10.1.1 Liquid Volume Check Prior to and After Autoclaving. To determine if liquid media is lost during autoclaving, mark a random sampling (approximately 5%) of tubes "V" (for volume check) prior to autoclaving. The volume of the media dispensed and autoclaved should be checked after autoclaving. Record the target volume, and the volume after autoclaving on the Liquid Media/Reagent Volume Check Before and After Autoclaving form. Calculate the percent difference. The percent difference should be within $\pm 5\%$ of the target volume for liquid media not used for enumeration. For liquid used for enumeration, the percent difference should be within $\pm 2\%$ of the target volume. If the percent difference exceeds the established difference, the batch will be discarded.
- 10.1.2 Liquid Media/Reagents in Tubes with Morton Closures. Liquid tubed media and reagents with Morton Closures can be stored at room temperature for up to 2 months in plastic bags. The media will be inspected for dehydration according to the instructions stated in 10.3.
- 10.1.3 Liquid Media in Capped Tubes or Bottles. Liquid media in tightly capped bottles or tubes may be stored for up to 3 months. The media in tubes will be inspected for dehydration according to the instructions stated in 10.3.
- 10.1.4 Reagents that are not very labile or are not harmed by long storage periods may be used for up to one year from the date of preparation. Reagents for which a recommended shelf life is known will be used within that time. Commercially prepared media and reagents will not be used beyond the manufacturer's expiration date.
- 10.2 Solid Media:
- 10.2.1 Solid Media in Plates. All media poured into Petri dishes will be stored in plastic bags at 2-5°C or at room temperature (refer to the media prep sheet for each media type). The plastic bags will be punctured in a few areas to allow air exchange and to reduce excessive condensation. Both selective and non-selective media may be stored for up to 3 months. After 3 months the media must

be discarded. Store all solid media in an upright (media side down) position in the refrigerator.

- 10.2.2 Solid Media in Tubes. Agar media in screw cap tubes or other sealed containers may be stored at 2-5 °C for up to 3 months. Both selective and non-selective media may be stored for this period of time. After 3 months the media must be discarded.

10.3 Inspection of Stored Media:

- 10.3.1 Solid Media in Tubes and Plates. Approximately 2 to 3 days prior to use, solid media will be inspected. If any discernible drying, cracking or contamination is present, the media will be discarded.

- 10.3.2 Liquid Media. Approximately 2 to 3 days prior to use, liquid media in tubes with Morton Closures stored longer than one month or two months for screw caps will be inspected. The fluid level will be checked in approximately 5% per batch and/or per rack of media to be used in testing to determine if more than 5% of the fluid has evaporated. If less than 5% of the solution has evaporated, the media can be used. If more than 5% has evaporated, the media will be discarded.

10.4 Performance and Sterility of all Purchased or Prepared Media/Reagents:

- 10.4.1 All prepared and purchased media and reagents will undergo sterility and performance verification according to guidelines stipulated in SOP QC-11, Performance and Sterility of Media and Reagents.

11.0 DATA ANALYSIS/CALCULATIONS:

- 11.1 Calculate the percent difference due to evaporation or loss during autoclaving. The percent difference is determined using the formula:

$$\text{Percent Difference} = 100\% - [(\text{Measured Volume} / \text{Target Value}) \times 100]$$

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

- 12.1 Data will be recorded promptly, legibly, and in indelible ink on the appropriate forms. Completed forms are archived in notebooks kept in secured file cabinets

in the file room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 For quality control purposes, the required information is documented on the appropriate record form(s) (see 16.0).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Expired media or that which has measurably lost more than 5% of the target volume is not to be used.

15.0 REFERENCES: None

16.0 FORMS AND DATA SHEETS:

16.1 Check of Stored Solid Media

16.2 Liquid Media/Reagents Volume Check Before and After Autoclaving

16.3 Volume Check for Stored Liquid Media and Reagents

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Check of Stored Solid Media

OPP Microbiology Laboratory

[illegible]

*Save or Discard

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Liquid Media/Reagents Volume Check Before and After Autoclaving

OPP Microbiology Laboratory

[illegible]

*Save or Discard

Volume Check for Stored Liquid Media and Reagents

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[illegible]

*Save or Discard

Discard if % dehydration is $\pm 5\%$ for media not used for enumeration.
Discard if % dehydration is $\pm 2\%$ for media used in enumeration.